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EXAMINER	
BUI, KIM T	

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,128	LAURYSSEN ET AL.	
	Examiner	Art Unit	
	Kim T. Bui	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/08/02&11/04/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

(A) As per claim 1, a visual representation, an audio component and a textual component of claim 1 do not represent structural components of a system claim. As such, except for the single means "input means", it is unclear what are the structures of the system. Also, the preamble of the claim recite system for "obtaining informed consent from a patient", however, the body of the claims fail to recite any structure to support this function recited in the preamble.

"The graphic representation", on line 6 of claim 1 lacks clear antecedent basis.

(B) As per claims 5,6, it is unclear what element(s) of the claims is "the web based " or "available twenty four hours a day".

(C) As per claims 7,14, "the patient's acknowledgment" on line 2 lacks clear antecedent basis.

(D) As per claim 8, there are no structural elements in the system of claim 8. "A visual representation", "the auditory component" and "textual component" of the claim do not represent any hardware or software. Also, the body of the claims fail to recite

how the "obtaining informed consent from a patient" function in the preamble is accomplished.

(E) As per claims 12,13, independent claim 8 fails to recite any structure. As such, it is unclear what element(s) of the claims is "web based" or "available 24 hours".

(F) As per claim 15, "wherein.....consent system" on lines 8, 9 of claim 15 is unclear. There is structure for the single informed consent system. Also, the body of the claim fails to recite how the "obtaining informed consent from a patient" function in the preamble is accomplished.

(G) As per claim 20, the body of the claims fail to recite how the "obtaining informed consent from a patient" function in the preamble is accomplished.

(H) As per claims 28, 30, the claims recite system and method for tracking outcomes, however, there are no steps or means in the body of the claims to perform the tracking function.

Dependent claims 2-4,9-12,16-19,21-27,29, 31 incorporate the deficiency of the claim they depend on and are therefore rejected.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-3, 5-10,12-23, 30-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts. The body of the claim(s) must recite how the technological art is employed to produce a useful, concrete and tangible result in a non-trivial manner. In the present application, the recited steps and means of the claims are merely for displaying surgery, summary, providing narrative and requesting acknowledgement, and do not apply, involve, use, or advance the technological arts since all of the recited means and steps can be performed in the mind of the user or by use of a pencil and paper. These claims are therefore constitute only an idea of how to obtain acknowledgment from a patient. In addition, for a claimed invention to be statutory, it must produce a useful, concrete, and tangible result. In the present case, claims 1-3,5-10,12-23,30-31 fail to recite a concrete useful and tangible result. (A) Claim 1 and dependent claims 2-3,5-7 fail to recite a useful, concrete and tangible result.

(B) Claim 8 and dependent claims 9-10, 12-14 fail to recite technological art and/or useful, concrete and tangible result.

(C) Claims 15-19 fail to recite technological art and/or useful, concrete and tangible result. Claim 17, in particularly, does not positively recite the "outcome" and fails to be within a technological art.

(D) Claims 20-23, 30-31 fail to recite technological art and/or a useful, concrete and tangible result.

The technological art (i.e. electronically storing) in the dependent claims 7,14,19,23, 31 is trivial.

In addition to the above, the "visual representation", "auditory component" and "text component" of claims 8-23 are considered to be "non-statutory non-functional descriptive material".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5-10, 12-16, 18-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Portnoy et al. (US2002/0062228 A1).

(A) As per claim 1, Portnoy et al. discloses a system for obtaining consent from a patient undergoing a surgery, comprising:

a. a video/ pictorial representation of the surgery. Portnoy et al., page 1, paragraph 0008, page 2, paragraph 0012, page 4, paragraph 0043, Fig. 13.

b. an auditory component integral with the visual representation, the audio component comprising a narration explaining the visual representation. Portnoy et al., page 2, paragraph 0012, page 4, paragraph 0043.

c. a textual component integral with the video/pictorial (i.e. graphic) representation and the auditory component, the textual component comprising a summary of each complication associated with the surgery. Portnoy et al., page 3, paragraph 0035, page 4, paragraph 0044, Fig. 13.

d. input means for inputting an acknowledgment of each complication. Portnoy et al., page 2, paragraphs 0013, 0028, page 4, paragraphs 0040, 0044

(B) As per claim 8, Portnoy et al. discloses a system for obtaining informed consent from a patient undergoing a surgery, comprising:

a. a three dimensional visual representation of the surgery. Portnoy et al., page 1, paragraph 0008, page 2, paragraph 0012, page 4, paragraph 0043, page 5, paragraph 0049.

b. an auditory component integral with the visual representation. Portnoy et al., page 2, paragraph 0012, page 4, paragraph 0043.

c. a textual component integral with the visual representation of the auditory component, the text component comprising summary of each complication associated with the surgery. Portnoy et al., page 3, paragraph 0035, page 4, paragraph 0044.

(C) As per claim 15, Portnoy et al. discloses a method for obtaining informed consent from a patient undergoing a surgery, comprising

a. displaying the surgery visually to the patient. Portnoy et al., page 1, paragraph 0008, page 2, paragraph 0012, page 4, paragraph 0043.

b. providing narration to accompany the visually displayed surgery. Portnoy et al., page 2, paragraph 0012, page 4, paragraph 0043.

c. displaying a summary of each complication associated with the surgery. Portnoy et al., page 3, paragraph 0035, page 4, paragraph 0044.

e. requesting acknowledgment from the patient of each complication, wherein the visual representation, the narration, the summary, and the acknowledgment request are integrally combined in a single informed consent system. Portnoy et al., page 2, paragraphs 0013, 0028, page 4, paragraphs 0040, 0044,

(D) As per claim 20, Portnoy et al. discloses a method for obtaining informed consent from a patient undergoing a surgery, comprising

a. displaying the surgery visually in a three dimensional form to the patient. Portnoy et al., page 1, paragraph 0008, page 2, paragraph 0012, page 4, paragraph 0043, page 5, paragraph 0049.

b. providing narration to accompany the visually displayed surgery. Portnoy et al., page 2, paragraph 0012, page 4, paragraph 0043.

c. displaying a summary of each complication associated with the surgery. Portnoy et al., page 3, paragraph 0035, page 4, paragraph 0044.

e. requesting acknowledgment from the patient of each complication. Portnoy et al. , page 2, paragraphs 0013, 0028, page 4, paragraphs 0040, 0044.

(E) As per claim 28, Portnoy et al. discloses a system for tracking outcomes of surgeries, comprising:

a. display means for displaying all of the complications associated with each surgery. Portnoy et al., page 1, paragraph 0008, page 8, claim 7.

b. means for identifying complications of a surgery encountered by a patient. Portnoy et al., Fig. 5, page 8, claim 7, page 10, claim 33.

c. means for automatically determining complication rate (i.e. recurrence rate) based on at least the identified surgery, its associated risk and complications. Portnoy et al. , page 4, paragraph 0044, page 8, claim 7, Fig. 5.

(F) As per claim 30, Portnoy et al. discloses a method for tracking outcomes of surgeries, comprising:

a. identifying the complications for a surgery encountered by a patient; and automatically determining a complication rate (i.e. recurrence rate) based on an application of information including at least the identified complications. Portnoy et al., page 4, paragraph 0044, page 8, claim 7, Fig. 5.

(G) As per claims 2, 16, 21, Portnoy et al. teaches three-dimensional visual representation on page 5, paragraph 0049.

(H) As per claims 5, 6, 12, 13, Portnoy et al. teaches the Internet and web-based application on page 3, paragraph 0030, page 5, paragraph 0055, page 6, paragraphs 0066, 0070, page 7, paragraph 0075.

(I) As per claims 7, 10, 14, 19, 23, Portnoy et al. teaches the steps and means for inputting and storing patient acknowledgment of the relevant aspect(s) of the surgery, information including the associated risk and complications. Portnoy et al., page 2, paragraphs 0013, 0028, 0029, page 4, paragraphs 0040, 0044, page 6, paragraph 0069, page 9, claim 14, Figs. 1, 8.

(J) As per claims 24, 26, Portnoy et al. teaches means for identifying each complication which the patient encountered during the surgery, storing means for storing the identified complications, and means for automatically determining a complication rate based on the identified complications. Portnoy et al., page 4, paragraph 0044, page 8, claim 7, Figs. 1,5,8, page 2, paragraphs 0013, 0028, 0029, page 4, paragraphs 0040, 0044, page 6, paragraph 0063, 0069, page 9, claim 14.

(K) As per claims 25, 27, 29, 31, Portnoy et al. storing means for storing surgery information, such as description of the injury, anatomy related to the problem (i.e. surgery information), and list of different medical procedures, such as lumber disk surgery (i.e. surgery type). Portney et al., page 3, paragraph 0037, page 4, paragraph 0041, page 6, paragraph 0063, the determined complication rate (i.e. recurrence rate) is further based on at least one of the surgery information (i.e. injury, type, its associated risk and complications).

(L) As per claims 3, 9, 18, 22, Portnoy et al. teaches that repeat information or further information/ additional information can be request regarding a particular aspect of the procedure (i.e. viewing anatomy, procedure itself, tests, risks and complication etc..). Pournoy et al, page 5, paragraph 0047.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 4,11,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portnoy et al. (US2002/0062228 A1) in view of Martin et al (5867247).

(A) As per claims 4, 11, 17, Portnoy et al. fails to expressly recite "outcome determination means". Portnoy, however, suggests a post operation module to describe and present what the person can expect to experience after the surgery. Portnoy et al. , page 4, paragraph 0045, Fig. 6. In addition, Martin et al discloses a patient consent system wherein the result of the surgery can be determined by simulation and the patient can be objectively apprised of how the surgery could affect post-operative vision prior to the surgery performed on the eyes. Martin et al, col. 2, lines 8-50. It would have been obvious to one having ordinary skill in the art at the time of the invention to include results/outcomes presentation to the patient with the motivation of better educating the patient on the surgery and thereby minimizing dissatisfaction and complaint. Martin et al, col. 2, lines 17-21, lines 31-35.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. " Computer accessible methods for informed consent" (6516300);

"Health education system" (4360345), " Video, photographs, and patient consent", Hood Catherine A., March 28, 1998, "British Medical Journal", 316, 7136, 1009, Dialog File 149, Acc. no. 01846814.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim T. Bui whose telephone number is 703-305-5874. The examiner can normally be reached on Monday-Friday from 8:30A.M. to 5:00P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KTB
02/04/05

ALEXANDER KALINOWSKI
PRIMARY EXAMINER